IN THE DISTRICT COURT 103RD JUDICIAL DISTRICT
CAMERON COUNTY, TEXAS

SANDRA GARCIA,	)	
	)	
Plaintiff,	)	Cause No.
	)	
vs.	)	2013-DCL-3511-D
	)	
RODOLFO J. WALSS, M.D.,	)	
RODOLFO J. WALSS, M.D., P.A.,	)	
JOHNSON & JOHNSON, INC. and	)	
ETHICON, INC.,	)	
	)	
Defendants.	)	
_____	)	

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Deposition of JOHN R. MIKLOS, M.D., taken on behalf of the Defendants, pursuant to Notice and agreement of counsel, before Judith L. Leitz Moran, Certified Court Reporter, at Butler Snow LLP, 1170 Peachtree Street, Suite 1900, Atlanta, Georgia, on the 6th day of February 2015, commencing at the hour of 9:15 a.m.

— — —

GOLKOW TECHNOLOGIES, INC.
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ownership interest in?

A Yes.

Q And what are those?

A RockHard Laboratories.

Q Any others?

A Not that I can think of right now.

Q When did RockHard Laboratories cease to exist?

A In the last five or six months.

Q Does it still exist as a corporate entity?

A Yes.

Q But it stopped functioning in the last six months?

A Well, it's been renamed as Food, Drug & Mass.

Q Ah. So whatever was going on in RockHard Laboratories was merged into Food, Drug & Mass?

A Yes.

Q Where is that company organized under, what state law?

A I believe it's Delaware.

Q And what work -- are you the sole owner of that company?

A No.

Q Who else has an ownership interest in it?
A Joshua Maurice and Jeff Remmel?
Q I didn't hear Jeff's last name?
A Remmel.
Q R-E-M-M-E-L?
A Yes.
Q Where does Mr. Maurice live?
A In Atlanta.
Q He is a physician?
A No.
Q Does he have a business other than Food, Drug & Mass?
A No. It looks like he will have that business. He's looking to buy the company from me.
Q He's looking to buy a company?
A He's looking to buy Food, Drug & Mass from me so it can be his sole ownership.
Q Okay. And where does Jeff Remmel live?
A Atlanta.
Q And does he have a job or business other than his ownership in Food, Drug & Mass?
A Yes.
Q What does he do?
A He works for myself and Dr. Moore and basically he's our CFO and our accountant.

Q And our accountant?

A Our accountant.

Q I'm sorry, when he's turning the pages, I just lose --

MR. LUNDQUIST: Oh.

MS. SMITH: It's not -- it's all right, you can do it, but I just lose the ability to hear his words.

BY MS. SMITH:

Q All right. And when did Food, Drug & Mass when was it first incorporated?

A I believe I answered that, was four to five months ago.

Q Okay. You said that's when RockHard Labs ceased to exist. I didn't realize it was at the same time. And what work -- what is Food, Drug & Mass, what is that company?

A It's a company that puts products on the shelves in food and drug stores.

Q And what does the mass relate, what's that word relate to?

A Massive stores, massive -- I believe it means massive box stores, like, Targets, et cetera.

Q And what products currently are put on the shelves through the company Food, Drug & Mass?

A We currently have still RockHard Weekend.

Working with Dr. Berman, the sexologist out of Chicago, and helping putting her products on the shelf, as she's currently I think on the shelves electronically with Wal-Mart and Target. And looking to get them into the stores, Wal-Mart, Target, Rite Aid, et cetera.

And we're currently looking -- we actually have -- looking to put on the shelves, and I believe we've already got them on some smaller shelves, Silver Biotics.

Those are the three main products right now.

Oh, and a natural lubricant for women that -- I don't know if it's made to any shelves yet.

Q What's the name of it?

A The name's escaping me right now.

Q Any other products whether they're your primary or not?

A That's all I can think of right now.

Q And did RockHard Laboratories have any products other than those that you've just listed?

A Yeah, they had Pandora, which was a female excitement drug. Or I'm sorry, not drug.

A Yes.

Q About the middle part, Mesh bladder sling surgeries (sling surgery bladder) are considered the Gold Standard for care -- of care for urinary leakage.

Do you agree with that?

A Yes.

Q These include the TVT sling, the TOT sling, and the newer Single-incision slings or Mini-slings.

Do you agree with that?

A Yes.

Q Bladder sling complications are very low and the FDA specifically did not include mesh bladder slings in their recent safety notification.

Do you agree with that?

A No, because it was included on their FDA notification.

Q Do you agree bladder sling complications are very low?

A In certain individual's hands and in certain products, yes.

Q And we're going to get to the FDA. But you're familiar with the 2008 and 2011 publications?

A I'm familiar with them, yes.

Q And did either of them advocate not to use the mid-urethral slings used in synthetic mesh for treatment of stress urinary incontinence?

A No, they did not advocate not to use them.

Q The FDA as well as the American Urogynecology Society and the Society of Female Urology have all stated that complications for mesh bladder sling are minimal.

Do you agree with that?

A Yes.

Q They are safe and effective and considered a Gold Standard treatment for female urinary leakage.

Do you agree with that?

A Yes.

Q And what does Gold Standard treatment mean?

A It's considered one of the premier choices for surgical efficacy with hopefully minimal complications.

Q Are you familiar with the term "Prolene polypropylene mesh"?

A Yes.

probably -- you're correct, have not.

Q All right. So that would be a true statement as of --

A That would be a true statement.

Q -- 2011?

A Yes.

Q All right.

A Okay, I think the rest I agree with.

Q All right. What do you -- and, again, as of 2011, what percentages would you have put in Bullet Point 3 as opposed to what is there?

It states, have been reported to be successful in approximately -- oh, excuse me -- Mesh sling surgeries for SUI have been reported to be successful in approximately 70 to 80 percent of the women at one year, based on women's reports and physical exams.

You said you disagreed with the percentage?

A Yes.

Q And what percentage do you think was accurate in 2011?

MR. LUNDQUIST: Object to form.

A At one-year follow-up, I believe 90 percent is the correct answer --

BY MS. SMITH:

Q Okay.

A -- in skilled surgeon's hands.

Q Okay. All right. And then in the last paragraph, just to make sure I understand, you agree with everything in it except two things.

One is, you do not believe vaginal scarring has ever been reported or is a complication that can occur following a non-mesh surgical repair for SUI; is that true?

A It is true if we're talking about the other Gold Standard being a Burch procedure. I don't know what other surgical procedures they're talking about. There's over 300 operations for stress incontinence.

Q Okay. Can vaginal scarring be a complication following a non-mesh surgical repair for SUI?

A I don't know how, no.

Q And you're not limiting it only to Burch --

A Well, I don't --

Q -- is that correct?

A -- I don't know all the other surgical procedures that are out there. And if they're

A No, I think that's it.

Q Do you agree it's a judgment call by the treating surgeon based on his or her own training and experience as to whether to use a surgical mesh for treatment of stress urinary incontinence from the transobturator approach, the retropubic approach or the use of a mini-sling?

A Yes, it is.

Q And Doctor, I want to show you another page from your current website marked as Exhibit 17.

(Miklos Deposition Exhibit 17 marked.)

BY MS. SMITH:

Q And ask first if you can identify that as being from your website, your current website?

A Yes, it is.

Q All right. We'll take a minute and let you review it and then I want to know if there is any part of it with which you disagree as you sit here today?

A (Witness reviews document.)

Yes, okay.

Q Is there any part of Exhibit 17 with which you disagree as you sit here today?

A Yes.

Q What?

A There are two main types of mini-slings, Bullet Point 1, Secur made by Gynecare whose cure rate average in the 60 to 70 percent range.

Q You disagree with that?

A Yes.

Q Okay. First off -- well, sitting here today, what is wrong with that sentence?

A What's wrong with that sentence is that the many, many studies show cure rates much lower than that.

Q Okay. Some studies show them higher than that, correct?

A But --

Q I mean, correct?

A -- with very, very short-term follow-up.

Q Is the answer yes or no to my question?

A Yes.

Q Okay. So --

A With very short-term follow-up.

Q Do you know when you wrote this?

A I didn't write this.

Q Do you know who wrote it in your group?

A Yes, it looks like Dr. Moore.

Q Because his name appears first in the

Q Go ahead.

A (Witness reviews document.)

Okay.

Q Anything else you disagreed with in Exhibit 17?

A No.

(Miklos Deposition Exhibit 18 marked.)

BY MS. SMITH:

Q I want to hand you Exhibit 18. Is that the study you were just referring to under -- on the right-hand side, Presentation Number: 111 P.

A Yes.

Q Okay. And under Conclusions, were the conclusions that the TVT-Secur results of this study suggested it to be as efficacious as its predecessors?

A That's what the conclusion states and I disagree.

Q Were you part of this?

A I was part of the study, yes.

Q Did you write the abstract?

A I did not.

Q Did you read it back at the time it was written?

A I don't believe I did.

Q You don't think you ever saw it before today?

A No, I've seen it before today.

Q Did you ever write anyone to say you disagreed with that?

A No, I made my opinion very vocal that I disagree with the use of the TVT-Secur to Dr. Lucente.

Q Did you ever -- this is published in the Journal of Pelvic Medicine & Surgery, correct?

A Yes.

Q Did you ever write to the journal to say you disagreed with that statement?

A No, be -- this, no, I did not.

Q Okay.

A This is not submitted to Journal of Pelvic Medicine & Surgery. What this abstract is, is what was being presented at a meeting somewhere and then they put this into their journal. You see the Presentation Number: 111 P? I didn't know this was being presented somewhere.

MS. SMITH: Move to strike as nonresponsive.

BY MS. SMITH:

Q It was published in the Journal of Pelvic

Q All right. The mesh, just talking about the mesh, is that -- that's used in TVT-Secur, was that the same mesh that you had been using since the original TVT slings -- since you started using them in the late '90s?

A It's the same mesh, but it's cut with a laser versus mechanically cut which changes the properties of the mesh.

Q Oh, have you seen the studies on that?

A No, I have not.

Q So do you have any basis to say it changes the properties?

A Well, the internal documents of Gynecare that states that using a laser will actually decrease fraying.

Q Uh-huh.

A And they haven't done any studies on that.

Q Have you seen any of the studies that were done, not emails, but actual studies? I didn't see them in your documents, and I could have missed it. But have you seen any of the studies on laser cut mesh versus mechanical cut?

A No.

Q You don't have any problem with laser cut

mesh, do you?

A I don't know.

Q Okay.

A Because it hasn't been utilized enough to study.

Q Okay. It hasn't been utilized enough to study, is that what you said?

A Yeah, in the sling format.

Q So you have no opinion one way or the other on laser cut versus mechanical cut mesh?

A I have an opinion that if we're going to make an issue out of it, that we need to look at the literature over it.

Q I don't want to make an issue out of it. Are you making an issue out of it?

A I'm just telling you what I feel.

Q Well --

A You asked me a question.

Q I know.

A I answered the question.

Q You don't have any scientific basis to say that the laser cut mesh is any different as it reacts in the human body as compared to the mechanical cut mesh?

A No, you're correct.

Q Okay.

A That I said from the beginning, the mesh used for the mini-sling, I don't agree with that statement, it's the same mesh we've been using for 10 years now on a suburethral sling. It works well for laymen, but it doesn't necessarily mean it's the exact same mesh.

Q All right. Do you agree that the polypropylene -- the Prolene polypropylene mesh is the best tolerated material to date with the least amount of complications?

A Yes, I do agree.

Q Do you agree that issue -- that as to the Prolene polypropylene mesh issues such as infection or rejection of the material are very, very rare?

A Yes, in a skilled surgeon's hands.

Q Do you agree with the Prolene polypropylene mesh that tissue ingrowth occurs rapidly?

A Yes.

Q Going back to the first page of Exhibit 19, the one you're on. Very first paragraph. Would the words used in that paragraph apply equally to TVT-Secur?

A No.

Q Which words would not?

A This decreases the risk of injury, however the sling is still able to go in the same position, i.e., mid-urethra in a tension-free manner.

Q Okay. What word do you -- word or words do you disagree with?

A No. 1, it's not tension free.

Q All right. Anything else?

A Yes. We're talking -- the actual procedure of the TVT-Secur did not set like a mini-sling does for a -- or the MiniArc sling.

Q All right. Well, let me ask it this way. Is there only one small incision needed in the vagina with the TVT-Secur?

A Yes.

Q Is it true that no incisions are needed in the groins or the abdomen and no needles are needed to pass through the abdomen or groins --

A Yes.

Q -- with the TVT-Secur?

A Yes.

Q Is it true with the TVT-Secur that having only one small incision decreases the risk of injury?

A Yes.

Q Is it true that the sling with the TVT-Secur is able to go in the same position mid-urethra?

A Yes, same position mid-urethrally, but not anchored laterally in the same position.

MS. SMITH: Move to strike as nonresponsive after "yes."

BY MS. SMITH:

Q Is it true that since there is no need for needle passage through the groins or abdomen, the procedure can very easily be done under local anesthesia in an outpatient setting or even in a procedure room setting in as little as 10 minutes in relation to the TVT-Secur?

A No.

Q Okay. What's not true about that?

A No. 1, the delivery -- the delivery system, the needle tip of the MiniArc, that is true. For the TVT-Secur, it's a razor sharp blade that has been noted to create more bleeding than other types of suburethral -- or mini incision slings.

Q All right. We're going to come to that, I promise you.

skilled hands and a skilled surgeon.

Q Okay. All right. Do you also have a blog where you -- that you consider part of your advertising?

A No.

Q Do you participate in any blog to your knowledge?

A I haven't participated in a blog for probably 8, 10 years that I know of.

Q Okay. Do you agree that degradation of mesh is a biocompatibility risk?

MR. LUNDQUIST: Form.

A I don't believe that I'm prepared to talk about biodegradability here today. I'm not an expert in biodegradation.

BY MS. SMITH:

Q All right. Do you believe inflammation is a biocompatibility risk or would it -- is that outside your area of expertise?

A No, inflammation is a biocompatibility risk.

Q Okay. Do you believe that contraction of the mesh is a biocompatibility risk?

A Yes, it is.

Q Do you believe scar tissue formation is a

biocompatibility risk?

A I would like to redact my statements. Each of these can be a risk, yes, not necessarily are a risk.

Q All right. Do you believe that scar tissue formation can be a biocompatibility risk?

A Yes.

Q Do you believe that erosion or extrusion can be a biocompatibility risk?

A Yes.

Q Do you believe infection can be a biocompatibility risk?

A Yes.

Q Do you have any other cases currently where you're involved as an expert witness other than the ones we discussed concerning mesh products?

A Repeat the question. Are you asking more mesh cases or --

Q No.

A I'm sorry.

Q Do you have any other cases currently where you're acting as an expert witness other than the mesh cases that we discussed previously, like, medical malpractice cases?

remember asking for it.

Q Do you know what role he played in this case?

A Yeah, it was more -- yeah, he saw Ms. Garcia for complaints of -- sounds like pain in her vagina. And --

Q Well, without details going through that, just -- you know he's a treating physician?

A Yes.

Q And do you know he's the doctor she's most currently seeing from the records you reviewed?

A Yes, I saw that in her depo.

Q Do you think his opinions as to her current state would have any significance to you?

MR. LUNDQUIST: Object to form.

A It certainly might.

BY MS. SMITH:

Q We discussed earlier that the FDA publication from 2008 made the statement that, Physicians should obtain specialized training for each mesh placement technique they use and be aware of its risk. Do you recall that?

A Yes.

Q Do you agree with that?

since your fellowship, correct?

A Yes.

Q And you've gone to training on many, if not all of them, before you used them?

A Yes.

Q All right. For the most part or maybe entirely, Doctor, do companies like Ethicon that sell surgical mesh for treatment of SUI sell directly to hospitals or surgery centers?

A Yes, I believe so.

Q And the same is probably true for many medical devices, correct?

A Yes.

Q Are you familiar with the credentialing committees at hospitals?

A Yes. At my hospital.

Q You've never been involved on the credentialing committee; is that correct?

A That's correct.

Q But do you agree one of their jobs is to make sure the doctors on staff are competent and qualified to perform the surgical procedures that they request to be able to perform?

MR. LUNDQUIST: Object to form.

A Can you repeat the question?

BY MS. SMITH:

Q Do you believe -- do you agree that one of the jobs of the credentialing committees at hospitals or surgery centers is to make sure the doctors are competent and qualified to perform the surgical procedures that they're seeking privileges for?

MR. LUNDQUIST: Form.

A I agree that's their job, but I -- from my experience, it's not well enforced.

BY MS. SMITH:

Q Okay. Do you agree it's the responsibility of the credentialing committee to not give privileges to perform surgical procedures unless the doctor can demonstrate by training or experience that he or she is competent to perform that procedure?

MR. LUNDQUIST: Object to form.

A Yes, I do agree.

BY MS. SMITH:

Q And Doctor, do you agree it's ultimately the individual physician's responsibility to make sure they're competent and qualified to perform a surgical procedure before they undertake to do so?

A Yes.

Q Do you acknowledge that medical device companies like Ethicon are not involved in the hospital credentialing process?

MR. LUNDQUIST: Object to form.

A Yes, they're not involved with the hospital credentialing.

BY MS. SMITH:

Q Do you acknowledge that Ethicon and similar medical device companies cannot tell hospitals which doctors they should give what privileges to?

MR. LUNDQUIST: Object to form.

A I'm sorry, repeat the question one more time.

BY MS. SMITH:

Q Do you acknowledge that medical device companies like Ethicon, it is not their responsibility or duty to tell hospitals how to give privileges to physicians?

MR. LUNDQUIST: Object to form.

A I agree that it's not the responsibility to tell the hospital, but I also believe that they may have a certain responsibility to choose and train physicians that are of quality.

BY MS. SMITH:

Q Okay. Do you have any reason whatsoever to believe Dr. Walss was not a quality physician?

A I do not.

Q Do you have any reason to believe he was not properly and adequately trained on the use of TVT-Secur?

A I do not.

Q You have no reason to doubt that?

A No reason to doubt that.

Q Now, are you aware of any requirement from any regulatory agency, the state or federal government, the FDA, anything that says a medical device company like Ethicon has a duty to train doctors on the use of their product?

MR. LUNDQUIST: Object to form.

A I am not familiar -- no, I am not familiar with any regulatory from FDA that says the companies must train the doctor.

BY MS. SMITH:

Q Do you acknowledge that Ethicon and medical device companies similar to Ethicon do undertake to offer courses and abilities for preceptorships to demonstrate to doctors how to surgically implant their products like surgical

BY MS. SMITH:

Q You acknowledge the FDA looked at it differently than you?

MR. LUNDQUIST: Object to form.

A Yes.

BY MS. SMITH:

Q And accepted that the TVT-O and TVT-R were predicate devices?

A Yes.

Q Are you an expert in FDA regulations?

A I am not an expert in FDA regulations, but I -- knowing more than the average layman about a 510(k), I'm an expert at least knowing that when it's submitted that you really need to clarify what you -- what the predicate device is and how it's similar or not similar to the device.

Q Well, the FDA as far as you know was familiar with the TVT-O and TVT-R --

A Yeah, but they weren't familiar with the TVT-Secur.

Q -- is that correct?

A Yes.

Q And they were familiar with the TVT-O and TVT-R at the time the 510(k) application was made on TVT-Secur?

Q You're also not an expert on law, are you?

A No, I don't know more than the average person.

Q All right. You recognize there are individuals with expertise based on their training and experience in biomaterials, correct?

A Repeat the question.

Q You do recognize there are individuals who have more expertise than you on biomaterials based on their education and experience?

A Yes, but not in the application -- there are people -- but I believe I have great expertise in the application of the biomaterial to the human body, specifically in women and pelvic floor dysfunction.

Just because you're an engineer and you understand biomaterials, it doesn't mean that you understand the application to the human body.

MR. LUNDQUIST: Move to strike after the word "yes."

BY MS. SMITH:

Q Do you have any training in biomaterial medical device design?

A Have I been trained, no.

Q Or in medical device development?

A No training, no.

Q Have you been involved in any bench research on polypropylene mesh?

A No.

Q Do you have any training or education in polymer chemistry?

A No.

Q Is misbranding a safety risk for medical devices?

A Repeat the question.

Q Is misbranding a safety risk for medical devices?

MR. LUNDQUIST: Object to form.

A Please define "misbranding."

BY MS. SMITH:

Q If you don't have a -- do you have a definition for it?

A No. I'm hoping you have a working definition because you asked the question.

Q The way this works is I ask questions. If I ask a question and you don't understand what the word means, you just say you don't know because you don't understand that word. I can't -- I'm not -- I can't answer your questions.

A She really hasn't been evaluated recently from her deposition.

Q All right, I'm going to get to that in just a moment.

But would it be fair to say the mesh that might -- that was involved in coming -- when the suture line broke down and the mesh fibers Dr. Walss saw, that could have happened regardless of the type of medical or the type of mesh device used?

MR. LUNDQUIST: Object to form.

BY MS. SMITH:

Q I mean, that occurs --

A Yes.

Q Okay.

A But with qualification. We now know after a Cochrane review, which is the biggest series of review of randomized clinical trials of single-incision meshes, that the TVT-Secur has a greater erosion rate than just about any other sling out there.

MS. SMITH: Move to strike as nonresponsive after "yes."

BY MS. SMITH:

Q When you have a breakdown at the suture

risk of mesh erosion through the vaginal epithelial based on the Cochrane review by Jeffrey Sanders, based on the Hota study, and based by internal documents that we've seen in -- with discussions of surgeons from Australia, Germany and Finland.

MS. SMITH: Move to strike after "yes" as nonresponsive.

BY MS. SMITH:

Q Have you ever read about or heard or experienced an occasion where mesh extruded through a suture line when you were using a TVT-R or when a TVT-R product was being used?

MR. LUNDQUIST: Form.

A Have I ever read or seen --

BY MS. SMITH:

Q Or -- correct?

A Yes.

Q Same true with the AMS product?

MR. LUNDQUIST: Form.

A Yes.

BY MS. SMITH:

Q And when you say there's a greater risk when it's the TVT-Secur, can you quantify that risk?

A It is -- the risk is statistically

significant, but I can't give it a quantification. I've seen risk rates of where in one study it was 19 percent versus 0 percent for a TVT-O.

Q One study?

A Right. And then, again, Jeffrey Sanders, who did the Cochrane review, which is the biggest review of 310 studies, 3258 patients, and reviewing all of the randomized clinical trials, they pulled out all the single-incision sling papers, which there are only five, four of which were single-incision slings by TVT-Secur.

And it was statistically significant that it had a lower cure rate of efficacy and a higher rate of extrusion, a higher rate of erosion, and a higher rate of blood loss.

MS. SMITH: Move to strike after your initial response as being nonresponsive.

BY MS. SMITH:

Q My question to you is, can you give a percentage based on two randomized studies?

MR. LUNDQUIST: Object to form.

A That's not two randomized studies, first of all.

BY MS. SMITH:

Q Okay. Can you give a percentage based on

any type of scientific study? Do you have a percentage as you sit here today other than to say it's more?

MR. LUNDQUIST: Object to form.

A It's more based on the best reviews out there, which is the Cochrane review which reviews all the literature. I do not have a specific number.

MS. SMITH: Okay. Move to strike as nonresponsive.

BY MS. SMITH:

Q Based on everything you've read, can you give me any percentage of what the risk is different compared -- comparing TVT-Secur, TVT-O and TVT-R?

MR. LUNDQUIST: Object to form.

A No.

MR. LUNDQUIST: Why don't we take a five-minute break and we can go into the home stretch here.

MS. SMITH: All right, if you -- yes, we can. Please don't make it 15 again.

MR. LUNDQUIST: Might be 10, but it definitely won't be 15.

MS. SMITH: Oh, please not 10, we've got

nonresponsive.

BY MS. SMITH:

Q Do you agree a competent doctor can correctly place the inserter and ultimately remove it without it sliding back out as you've described it?

MR. LUNDQUIST: Object to form.

A What sliding back out?

BY MS. SMITH:

Q I thought you said the inserter device slides back out?

A The inserting device does and it pulls the sling with it.

Q Okay. Can you answer my question?

A What percentage of -- I mean, the question is based on what percentage at the time.

Q No, that wasn't my question.

A A competent doctor -- they haven't proven to me they did it competently enough to get good results, so no.

Q And that again is not my question.

A No.

Q Do you agree there might exist on the planet earth a competent physician who can use the insertion device for TVT-Secur in such a way that

it doesn't slide back out?

MR. LUNDQUIST: Object to form.

BY MS. SMITH:

Q When you're not intending to pull it out?

MR. LUNDQUIST: Form.

A There's probably somebody on the face of the earth, yes.

BY MS. SMITH:

Q All right. Do you have any proof whatsoever in this case that Dr. Walss had any problem at all with the insertion device sliding back out?

A No.

Q You acknowledge there was no undue bleeding, correct?

A Correct.

Q And you acknowledge there's no nerve damage, correct?

MR. LUNDQUIST: Object to form.

A No.

BY MS. SMITH:

Q Do you have any proof whatsoever there is any nerve damage in this case?

A I know that she's suffering still with twinges and muscular pain.

Q Is it your testimony a surgeon inserting a TVT-Secur has to use this stylet combination?

A No.

Q Was it even used in this case?

A I don't know.

Q So you have no proof or no evidence whatsoever that there was any issue with the structure that Dr. Walss had in this case; is that correct?

MR. LUNDQUIST: Object to form.

A That's correct, I'm just basing it on the fact that that's how the device was taught.

BY MS. SMITH:

Q You're saying there might be some doctor somewhere at some time that had that problem, but you can't say it was an issue in any regard with Dr. Walss in his treatment of Ms. Garcia?

MR. LUNDQUIST: Object to form.

A Yes.

BY MS. SMITH:

Q All right. And then I think your last criticism of the design was the Ethisorb fleece caps, correct?

A Yes.

Q All right. Now, you acknowledge that the

Ethisorb -- I stumble over that every time -- is absorbable?

MR. LUNDQUIST: Object to form.

A Yes.

BY MS. SMITH:

Q So the only issue you would have, if any, is whether it helped with fixation, an efficacy issue, correct?

A Correct.

Q So there wasn't anything dangerous about the Ethisorb fleece; fair enough?

A Not dangerous, but decreases -- if it doesn't fixate appropriately, it's going to decrease your efficacy.

Q All right.

A And potentially lead to increased mesh erosion because you have buckling of the sling.

MS. SMITH: All right. Move to strike as nonresponsive.

BY MS. SMITH:

Q You agree there's nothing dangerous about the Ethisorb ends as they exist in the body?

A Not that I'm aware of.

Q All right. So your issue with them is they may not at times help at all with fixation of

the ends of the mesh in the fibroconnective tissue?
MR. LUNDQUIST: Object to form.
A Correct, it's never been studied.
BY MS. SMITH:
Q Okay. So you can't say they don't work, you can only say there's not a study that shows they do work --
MR. LUNDQUIST: Object to form.
BY MS. SMITH:
Q -- fair enough?
A Yes, Ethicon did not do a study that showed that it works.
Q All right. But is my question correct? You can --
A I said yes.
Q Okay. You know from reviewing all of the records and depositions you were provided that, and we're going to take this in stages, but at least up to Dr. Doctor's procedure, Ms. Garcia did not have recurrent stress urinary incontinence, true?
MR. LUNDQUIST: Object to form.
A Repeat the question, but I just want to also mention you never touched the releasing device.
BY MS. SMITH:

even see it in the internal memos from some of the European leaders that say, listen, you can't send somebody to training that doesn't do cystoscopy.

So sometimes the individuals were not even qualified from a surgical perspective to really be trained on this type of surgical procedure.

And this surgical procedure is so much harder to learn than the TVT and the TVT-O. It's really reserved for the elite of the elite if you're going to do TVT-Secur.

BY MR. LUNDQUIST:

Q So, in your opinion -- it would be your opinion that the Ethicon -- it would be your opinion that Dr. Walss should have continued to implant the TVT-O and not the TVT-S?

MS. SMITH: Object to form.

MR. McTAGGART: Object to form.

A I think that Dr. Walss should have stuck to a surgical procedure that has a higher cure rate because at that time it was well-known in 2012 that the cure rate of the TVT-O was much better than a TVT-Secur.

BY MR. LUNDQUIST:

Q But you don't --

C E R T I F I C A T E

STATE OF GEORGIA:

COUNTY OF FULTON:

I hereby certify that the foregoing transcript was taken down, as stated in the caption, and the questions and answers thereto were reduced to typewriting under my direction; that the foregoing Pages 1 through 345 represent a true and correct transcript of the evidence given upon said hearing, and I further certify that I am not of kin or counsel to the parties in the case; am not in the regular employ of counsel for any of said parties; nor am I in anywise interested in the result of said case. The witness did reserve the right to read and sign the transcript.

This, the 12th day of February 2015.

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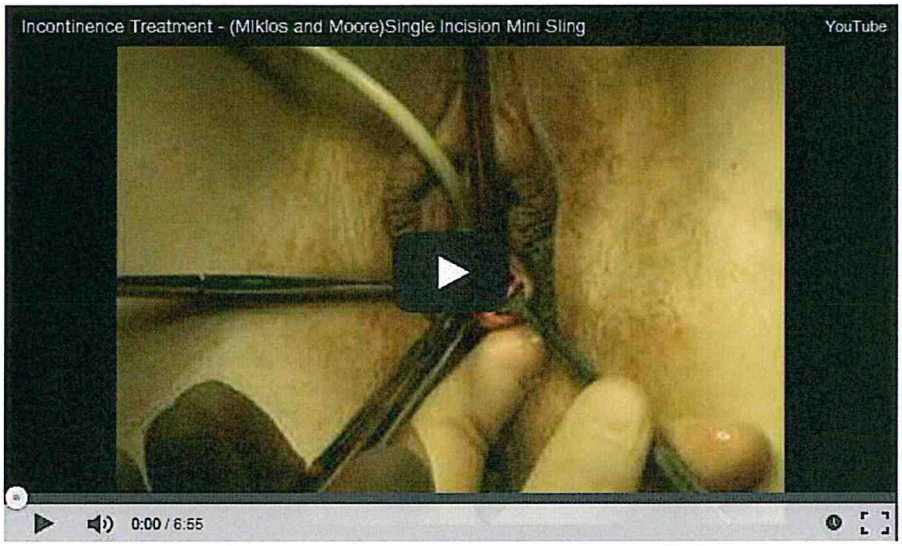
Judith L. Leitz Moran, CCR-B-2312

- Events / Public Relations
- Clinical Research Trials

Mini Sling for Stress Urinary Incontinence Treatment



The mini sling is a essentially a miniature sling delivered through a single incision site via the vagina. Most other slings require either two or three incisions. Both the **TVT** and **TOT** slings requires three incision sites, an incision in the vagina and two smaller exit incisions in the pubic area or the groins bilaterally. The mini sling was produced in an attempt to maintain cure rates yet minimize pain, blood loss, and voiding dysfunction post operatively.

There are two main types of **mini slings** are in circulation today:

- Secure made by Gynecare whose cure rates average in the 60-70% range
- MiniARC – made by American Medical System (AMS) whose cure rates are 90%.

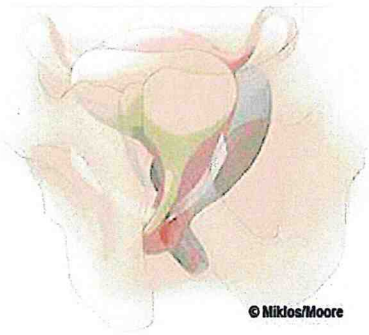


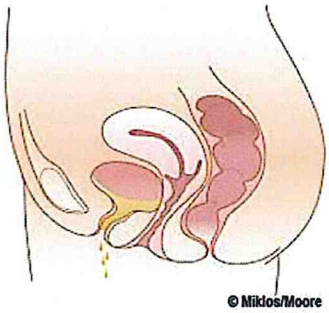
EXHIBIT: 17
NAME: Miklos
DATE: 2-10-2015
J Leitz Moran

Single Incision Mini-Sling: The next step in Minimally Invasive Treatment For SUI

Dr. Moore was the first surgeons in the United States to place the Mini-Arc mini-sling **(click here to view press release)**.

The **mini-sling procedure** utilizes the same concepts of the tension-free tape mid-urethral slings, however only one incision is needed and the procedure can be completed in as little as 5-10 minutes under local anesthesia!! The procedure was initially released in September of 2006 by Gynecare with a procedure called the TVT-Secure and Dr. Miklos and Moore were some of the first surgeons to evaluate and study the procedure. They liked the concept of a single incision sling, however were not enthused by the engineering and design of the Secure sling. In early 2007, with development input from Dr. Moore and Miklos, American Medical Systems made several improvements to the procedure and in April, Dr Moore was the first surgeon in the United States to place the Mini-Arc mini-sling (click here to view press release). Dr. Moore's and Miklos' center in Atlanta, because of their reputation of being world leader's in treatment for SUI, was chosen as the lead center in the USA to evaluate and study the Mini-Arc procedure. Dr. Moore was chosen as principal investigator, leading 5 centers in the USA and the world, to study and present the initial results in the USA, which have been excellent and very exciting! Since 2007, the results have continued to be impressive and it has become a mainstay in treatment in female SUI. Once again, Dr. Moore and Miklos were in the lead of bringing new technology to the field of female urology that has now become a procedure that has been adopted world-wide.

Dr. Moore, along with Dr. Miklos, in 2009, were the first in the world to publish longer term follow-up on patients that underwent the Mini-arc sling in the Journal of Surgical Technology (click here to view paper). They found a cure rate of over 90% at one year, which is consistent with other slings such as the TVT and the TOT sling and minimal risks of any complications. Dr. Moore is also **co-author of the largest multi-center trial completed to date in the world on the mini-arc mini sling** which was just published in the Journal of Urology in August of 2010. Consistent with their first paper, the multicenter trial (centers from all over the world were involved in this trial, along with Dr. Moore and Miklos' Center) showed an objective cure rate of over 90% with very low risk of voiding dysfunction (i.e. obstruction), pain, infection or other complications. Average hospital stay was less than 3 hours and return to normal activity was very rapid. Dr. Ty Erikson presented a study at the American College of Ob/Gyn that showed that almost 70% of women did not take ANY pain medication after having the procedure completed... another indication of how minimally invasive the procedure is.



As stated by the American Urologic Association consensus statement in 2001, there are only 2 procedures that are proven to have effective long-term cure rates for the treatment of stress urinary incontinence (SUI). These procedures are the abdominal Burch Colposuspension (or MMK) and the sling procedure that is completed vaginally. However, in the past, the sling procedure was far from standardized. There have been multiple different descriptions using different materials for the sling (fascia from the patient, cadaveric fascia or dermis from humans or animals, synthetics, etc), different anchoring points, and different methods to adjust the tension of the sling. In many cases patients had to undergo general anesthesia, were in the hospital for several days, required a catheter to drain the bladder coming out of the abdomen (because it took so long to void on their own) and many patients suffered high rates of voiding dysfunction following these slings.

However the introduction of the tension-free vaginal tape procedures to the United States in the late 90's revolutionized the treatment of SUI. It introduced a standardized sling procedure that could be completed safely in 20 minutes under local anesthesia, utilizing 3 very small incisions with minimal dissection, a cough test for individual tension patient adjustment and excellent cure rates. Over 1 million of these procedures have been completed worldwide. This procedure was called the TVT sling and since several other types of similar slings have been developed to try to improve on its safety.

Single Incision Mini- Sling- New, Safer Approach

Despite its relative safety, the original tension free vaginal tape procedures require the blind passage of needles through 2 small incisions in the abdomen just above the pubic bone. The retropubic space that the needle has to pass through to get to these abdominal incisions is also a very vascular space with venous plexuses and the potential for injury to large blood vessels in the pelvis. Secondary to this and the areas that the needle has to pass to place the mesh tape, there is potential for complications such as injury to the bladder, intestines, or nerves in the pelvis and/or abdomen. All of these injuries have been reported in the literature. Secondary to this, physicians in Europe began investigating to find a safer approach to place the mesh tape sling.

Mini Sling Surgical Technique Synopsis | **Mini Sling Results and Complications** | **Mini Sling Surgical Video**

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Conclusions: In this review, a transobturator sling utilizing a heavyweight hernia mesh was demonstrated to be effective for SUI with a self-reported cure/improvement rate of 94.9% at 22.6 months. However, 8.5% of patients experienced symptomatic mesh complications, considerably higher than most porous monofilament slings. Other issues such as de novo OAB and groin pain related to this iteration of a TO sling are raised. With the widespread use of sling "kits", the prospect for more cost effective solutions is attractive particularly in resource poor areas but warrants further investigation for the optimal sling mesh and delivery route, with attention to safety and sexual function.

Presentation Number: 110 P

Medium-Term Subjective and Objective Outcomes of the Suburethral Cooper's Ligament Sling

R. V. Ross, T. Duong, and R. Adam *Emory University Hospital, Atlanta, GA*

Objectives: This study evaluates the suburethral sling with attachment to Cooper's ligament to determine medium-term success rates by postoperative subjective and objective criteria.

Materials and Methods: A total of 50 patients were selected based on CPT codes for sling operations SUI and ISD. Seven had an abdominal sling with attachment to Cooper's ligament and 41 had a transvaginal suburethral sling with attachment to Cooper's ligament utilizing the Capio CL device (BS, Boston, MA). All available demographic, preoperative and postoperative clinical data were abstracted. Patients were asked to fill out a questionnaire that included the short versions of the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7). They were also requested to present for a physical examination and/or urodynamics. The student T-test was used to compare continuous variables while the McNemar test was used to compare dichotomous variables.

Results: Twenty-seven patients (58%) responded, 27 with vaginal and 2 with abdominal procedures. The mean age was 65.1 ± 9.4, with a mean parity of 2.8 ± 1.5 and a mean BMI of 27.8 ± 7.4. The mean valsalva leak point pressure (VLPP) at maximum cystometric capacity (MCC) was 59.3 ± 26.8. The mean follow up was 23 months (range 1 to 58 months). Nineteen patients filled out UDI-6 and IIQ-7 evaluations and had preand postoperative urodynamics. Eight patients had UDI-6 and IIQ-7 measurements in conjunction with a supine cough stress test. The remaining 21 charts of those who did not respond were reviewed and postoperative supine cough stress test results were recorded.

Subjectively, a mean preoperative UDI-6 value of 7.6 ± 3.4 and an IIQ-7 value of 6.1 ± 4.6 were both significantly lower than the postoperative values of 5.0 ± 3.8 and 2.1 ± 3.3 ($P = 0.01$ and $P = 0.001$). Objectively, a cough stress test was performed on all patients with 74% having a negative result. Of those patients who had urodynamics, 56% did not have urodynamic SUI. Several of the urodynamic parameters were unchanged after surgery including maximal urethral closure pressure, functional urethral length and presence of abnormal voiding mechanisms. While the VLPP at 200 mL was significantly lower in the prevs postoperative group (67.0 ± 36.6 versus 93.9 ± 17.0, $P = 0.04$), the difference at the MCC was not significant (59.1 ± 30.8 versus 68.8 ± 35.3, $P = 0.6$). The MCC was higher in the prevs postoperative groups (527.6 ± 201.7 versus 396.7 ± 182.4 mL, $P = 0.046$). Postoperatively, patients were more likely to have detrusor overactivity incontinence, 10% versus 17% ($P = 0.002$). In our study, 94% would recommend the procedure to a friend.

Conclusion: In our study of suburethral slings anchored to Cooper's ligament for ISD, significant subjective improvements were demonstrated. Objective data showed a 74% success rate in patients who had a supine cough stress test. Using urodynamics, the success rates dropped to 56%. This study suggests that when attached to Cooper's ligament, the suburethral sling may improve functional outcomes in women with SUI.

Presentation Number: 111 P

Multicenter Short Term Assessment of Patients Undergoing the Tension Free Vaginal Tape-Secur System for the Surgical Treatment of Female Stress Urinary Incontinence

S. M. Saltz,* G. Mitchell,† R. Haff,‡ K. Forster,† R. Moore,† J. Miklos,† and V. R. Lucente,§ **Institute of Female Pelvic Medicine & Reconstructive Surgery and St. Luke's Hospital & Health Network, Allentown, PA; †Atlanta Center of Laparoscopic Urogynecology, Alpharetta, GA; ‡St. Luke's Hospital & Health Network, Bethlehem, PA; §Institute of Female Pelvic Medicine & Reconstructive Surgery, Allentown, PA*

Objectives: The purpose of this study was to describe the short-term efficacy and peri-operative outcome associated with use of the new TVT-Secur pubovaginal sling for the treatment of stress urinary incontinence (SUI).

Methods: A retrospective chart review of 105 patients from 2 separate institutions with at least 6 week follow-up was performed. All patients had the procedure performed under local/regional anesthesia with sedation. A cough test or crede maneuver was used for setting the tape in most cases with empirical setting used in the minority. Operative data collected included OR time and estimated blood loss. Postoperative data collected included pain, voiding dysfunction, SUI, and OAB symptoms as well as subjective improvement.

Results: A total of 105 patients underwent correction with TVT-Secur. The average age was 60 years (±13.7) with a BMI of 29.7 (±6.0) and parity of 2.6 (±1.3). 62 patients (59.0%) underwent concomitant prolapse surgery at the time of sling placement. The mean OR time for TVT-Secur placement alone was 26.8 (±9.8) minutes and mean EBL was 51.3 (±41.0) ml. In total, 55 patients (52.4%) received the "U" placement while 50 (47.6%) received the "hammock" configuration. Of these, 75 (71.4%) displayed no postoperative SUI, 30 (28.6%) patients had persistent SUI, of which 20 (66.7%) were significantly improved compared with preop and did not desire further treatment. There were 10 (9.5%) true failures in which the patients experienced persistent SUI with a desire for further correction. New postoperative voiding dysfunction was recorded in 7 patients (6.7%) with 3 patients undergoing sling revision. Only 1 patient (0.95%) complained of pain at 6 weeks after a "U" placement which has since resolved. Compared with the overall cure rate, the last 25 patients demonstrated a higher cure rate of 80%, suggesting a surgical learning curve. There have been no mesh exposures.

Conclusions: Preliminary results of the TVT-Secur procedure suggest it to be as efficacious as its predecessors, the midurethral retropubic and transobturator pubovaginal slings, for the surgical treatment of SUI. There is a real surgical learning curve as demonstrated by the improvement in outcomes realized over time. The greatest clinical value offered by the new TVT-Secur is a significant decrease in postoperative pain as compared with the traditional retropubic and transobturator slings.